IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICA N.V., JANSSEN, L.P., and SYNAPTECH, INC.,	)	
Plaintiffs/Counterclaim-Defendants,	)	Civ. Action No. 05-371 (KAJ)
v.	)	
MYLAN PHARMACEUTICALS INC., and MYLAN LABORATORIES INC.,	)	
Defendants/Counterclaim-Plaintiffs.	)	

MYLAN PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S
ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan") answer the Complaint of Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs") as follows:

The Parties

1. Plaintiff Janssen Pharmaceutica N.V., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

ANSWER: Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and on that basis denies those allegations.

2. Plaintiff Janssen, L.P., a wholly owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

ANSWER: Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and on that basis denies those allegations.

3. Plaintiff Synaptech, Inc., ("Synaptech") is a company organized and existing under the laws of the State of New York and has its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

ANSWER: Mylan is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and on that basis denies those allegations.

4. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan Pharmaceuticals does business in the State of Delaware.

ANSWER: Mylan admits the allegations in the first sentence of Paragraph 4. Mylan further admits that Mylan Pharmaceuticals is subject to personal jurisdiction in this judicial district for purposes of this action only. Mylan denies the remaining allegations of Paragraph 4.

5. Upon information and belief, Defendant Mylan Laboratories Inc. ("Mylan Laboratories") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and having its principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317. Mylan Pharmaceuticals does business in the State of Delaware. Mylan Laboratories is the ultimate parent of Mylan Pharmaceuticals, and Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Laboratories.

ANSWER: Mylan admits the allegations in the first and third sentences of Paragraph 5. Mylan denies the remaining allegations of Paragraph 5.

6. Mylan Pharmaceuticals represents on its website that "[l]ast year, pharmacists filled more than 197 million prescriptions with products from Mylan, making it the #1 US-based manufacturer of generic pharmaceutical products." Upon information and belief, a proportionate number of those prescriptions were filled in Delaware, and last year more prescriptions were filled in the State of Delaware with products from Mylan Pharmaceuticals than from any other US-based manufacturer of generic drug products.

ANSWER: Mylan admits that Paragraph 6 contains an accurate but incomplete quotation from Mylan Pharmaceuticals' website. Mylan further admits that, last year, pharmacists filled prescriptions in the State of Delaware with drug products from Mylan

Pharmaceuticals. Mylan lacks sufficient information to admit or deny the remaining allegations of Paragraph 6 and thus denies all such allegations.

7. Upon information and belief, Mylan Pharmaceuticals and Mylan Laboratories collaborated in the research and development of Mylan's Abbreviated New Drug Application ("ANDA") No. 77-590 for galantamine hydrobromide tablets, continue to collaborate in seeking approval of that application from the Food and Drug Administration ("FDA"), and intend to collaborate in the commercial manufacture, marketing, and sale of galantamine hydrobromide products, including commercial marketing and sale in the State of Delaware, in the event that FDA approves Mylan's ANDA No. 77-590. Upon information and belief Mylan Pharmaceuticals and Mylan Laboratories collaborate in the manufacture, marketing, and sale of many pharmaceutical products, including numerous generic prescription drug products manufactured and sold pursuant to an approved abbreviated new drug application, that are marketed and sold to customers in the State of Delaware.

ANSWER: Denied.

8. Mylan has also availed itself of this forum for purposes of litigating its patent disputes. For example, in 2002, Mylan Pharmaceuticals filed a patent infringement action, Civil Action No. 02-1628, in the United States District Court for the District of Delaware concerning patents relating to generic omeprazole drug products. Upon information and belief, Mylan Laboratories collaborated in the decision to file suit and approved its filing.

ANSWER: Mylan admits that Mylan Pharmaceuticals filed a patent infringement action, Civil Action No. 02-1628, in the United States District Court for the District of Delaware concerning patents relating to generic omeprazole drug products. Mylan further admits that Mylan Laboratories collaborated in the decision to file Civil Action No. 02-1628. Mylan denies the remaining allegations of Paragraph 8.

Jurisdiction and Venue

9. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 4,663,318 ("the '318 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that this action purports to arise under the patent laws; that Plaintiffs' Complaint alleges infringement of U.S. Patent No.

4,663,318 ("the '318 patent"); and that this Court has subject matter jurisdiction over Plaintiffs' infringement claims on the patent-in-suit. Mylan denies the remaining allegations of Paragraph 9.

10. Mylan Pharmaceuticals is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business in the State, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with the State.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Mylan Pharmaceuticals is subject to personal jurisdiction in this judicial district for purposes of this action only. Mylan denies the remaining allegations of Paragraph 10.

11. Mylan Laboratories is subject to personal jurisdiction in this judicial district by virtue of, *inter alia*, its having conducted business is the State, having availed itself of the rights and benefits of Delaware law, and having engaged in substantial and continuing contacts with, the State.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan denies the allegations of Paragraph 11.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that venue is proper in this judicial district for Mylan Pharmaceuticals for purposes of this action only. Mylan denies the remaining allegations of Paragraph 12.

Regulatory Requirements for Approval of New and Generic Drugs

13. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 US.C. § 355(b). To secure approval of an NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the requirements for the approval of a new drug application ("NDA") are set forth in 21 U.S.C. § 355(b). Mylan denies that Plaintiffs have accurately characterized or fully described such requirements. Mylan denies the remaining allegations of Paragraph 13.

14. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the requirements for the approval of an Abbreviated New Drug Application ("ANDA") are set forth in 21 U.S.C. § 355(j). Mylan denies that Plaintiffs have accurately characterized or fully described such requirements. Mylan denies the remaining allegations of Paragraph 14.

15. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the requirements for the approval of an ANDA are set forth in 21 U.S.C. § 355(j). Mylan denies that Plaintiffs have accurately characterized or fully described such requirements. Mylan denies the remaining allegations of Paragraph 15.

16. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the requirements for the approval of an ANDA are set forth in 21 U.S.C. § 355(j). Mylan denies that Plaintiffs have accurately characterized or fully described such requirements. Mylan denies the remaining allegations of Paragraph 16.

17. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that 21 U.S.C. § 355(a) addresses the approval of an NDA or ANDA. Mylan denies that Plaintiffs have accurately characterized or fully described that provision. Mylan denies the remaining allegations of Paragraph 17.

Plaintiffs' Approved Drug Product

18. Janssen is the holder of an approved new drug application, NDA. No. 21-169, for galantamine hydrobromide tablets. That NDA was approved by FDA on February 28, 2001 and covers three strengths of tablet – Eq. 4 mg base, 8 mg base, and 12 mg base. The sole indication or condition of use for which galantamine hydrobromide tablets are approved in NDA No. 21-169 is the treatment of mild to moderate dementia of the Alzheimer's type.

ANSWER: Mylan admits that FDA's electronic Orange Book (current through May 2005) identifies Janssen Pharmaceutica as the applicant for NDA No. 21-169, approved February 28, 2001, for galantamine hydrobromide tablets 4 mg, 8 mg, and 12 mg. Mylan further admits that the approved indication or condition of use for galantamine hydrobromide is set forth in the Indications and Usage section of the current FDA-approved labeling. Mylan denies the remaining allegations of Paragraph 18.

19. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide tablets for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE®. Until this year, Janssen marketed galantamine hydrobromide tablets under the trademark REMINYL®.

ANSWER: Denied.

20. FDA has listed the '318 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-169.

ANSWER: Admitted.

21. The '318 patent qualifies for listing in the Orange Book in connection with NDA No. 21-169 because it claims an approved use of the drug product that is the subject of that NDA. Mylan has never challenged the listing of the '318 patent in the Orange Book.

ANSWER: The first sentence of Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan denies the allegations in the first sentence of Paragraph 21. Mylan admits the allegations in the second sentence of Paragraph 21.

Mylan's ANDA

22. Mylan has represented that on or before April 27, 2005, it submitted to FDA an ANDA (ANDA No. 77-590) and paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for galantamine hydrobromide tablets purportedly bioequivalent to Plaintiffs' RAZADYNE® products. The purpose of Mylan's ANDA and paragraph IV certifications is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide tablets before the expiration of the patents listed in the Orange Book for Janssen's NDA. No. 21-169. Hence, Mylan's purpose in submitting ANDA No. 77-590 is to market in the United States the galantamine hydrobromide products described therein before expiration of the '318 patent.

ANSWER: Mylan admits that Mylan Pharmaceuticals submitted to FDA an ANDA, which contains a paragraph IV certification, for the purpose of engaging in the commercial manufacture and sale of galantamine hydrobromide tablets before the expiration of

the '318 patent listed in FDA's Orange Book in connection with NDA No. 21-169. Mylan denies the remaining allegations of Paragraph 22.

23. Upon information and belief, the sole condition of use for which Mylan seeks approval in its ANDA No. 77-590 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in Janssen's NDA No. 21-169.

ANSWER: Mylan admits that the current proposed labeling in Mylan Pharmaceuticals' ANDA for galantamine hydrobromide tablets sets forth, among other things, the condition of use for which Mylan Pharmaceuticals is seeking approval. Mylan denies that Plaintiffs have accurately characterized or fully described such labeling. Mylan denies the remaining allegations of Paragraph 23.

24. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Mylan in its ANDA No. 77-590 for its proposed galantamine hydrobromide tablets is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for Plaintiffs' REMINYL® and RAZADYNE® tablets.

ANSWER: Mylan admits that the current proposed labeling in Mylan Pharmaceuticals' ANDA for galantamine hydrobromide tablets sets forth, among other things, the condition of use for which Mylan Pharmaceuticals is seeking approval. Mylan denies that Plaintiffs have accurately characterized or fully described such labeling. Mylan denies the remaining allegations of Paragraph 24.

Count 1: Patent Infringement

25. Plaintiffs reallege paragraphs 1 through 24 above as if fully set forth herein.

ANSWER: Mylan reasserts and incorporates by reference each of its answers to Paragraphs 1-24.

26. On May 5, 1987, the United States Patent and Trademark Office duly and legally issued the '318 patent, entitled "Method of Treating Alzheimer's Disease." The term of the '318 patent runs through December 14, 2008. A true and correct copy of the '318 patent is attached hereto as Exhibit A.

ANSWER: Mylan admits that the United States Patent and Trademark Office ("PTO") issued the '318 patent, entitled "Method of Treating Alzheimer's Disease," on May 5, 1987, and that a copy of the '318 patent is attached to the Complaint as Exhibit A. Mylan denies that the '318 patent was "duly or legally issued." Mylan denies the remaining allegations of Paragraph 26.

27. Synaptech is the owner of the '318 patent.

ANSWER: Mylan admits that Synaptech purports and claims to own the '318 patent. Mylan further admits that, according to the electronic assignment records of the PTO, Synaptech is the assignee of the '318 patent. Mylan denies the remaining allegations of Paragraph 27.

28. Janssen is the exclusive licensee under the '318 patent, pursuant to an exclusive license agreement between Synaptech and Janssen, of the right to develop, make, have made, keep, use, market, sell, and/or dispose of certain pharmaceutical preparations containing galantamine hydrobromide to treat Alzheimer's disease in the United States and other territories. Pursuant to that exclusive license, Janssen currently markets galantamine hydrobromide tablets in the United States under the trademark RAZADYNE® and previously marketed galantanaine hydrobromide tablets in the United States under the trademark REMINYL®. The conditions of use for which RAZADYNE® and REMINYL® are approved fall within one or more of the claims of the '318 patent.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan lacks knowledge or information sufficient to admit or deny the allegations in the first sentence of Paragraph 28 and thus denies all such allegations. Mylan denies the remaining allegations of Paragraph 28.

29. As exclusive licensee, Janssen is authorized to enforce the '318 patent.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan lacks knowledge or information sufficient to admit or deny the allegations of Paragraph 29 and thus denies all such allegations.

30. The conditions of use for which Mylan seeks approval in its ANDA No. 77-590 fall within one or more of the claims of the '318 patent. If approved, use of Mylan's proposed galantamine hydrobromide products in accordance with the proposed labeling for those products submitted in ANDA No. 77-590 would constitute a use of the product claimed in one or more of the claims of the '318 patent.

ANSWER: Denied.

31. Mylan Pharmaceuticals is liable for infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 77-590 with a paragraph IV certification seeking FDA approval of ANDA No. 77-590 prior to expiration of the '318 patent. Mylan Laboratories is liable for infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its causing ANDA No. 77-590 with a paragraph IV certification to be filed with FDA seeking approval of ANDA No. 77-590 prior to expiration of the '318 patent.

ANSWER: Denied.

32. Upon information and belief, if approved, Mylan's galantamine hydrobromide products for which approval is sought in Mylan ANDA No. 77-590 will be administered to human patients in a therapeutically effective amount for treatment of mild to moderate dementia of the Alzheimer's type, which administration would constitute direct infringement of the '318 patent. Upon information and belief, this infringement will occur at Mylan's behest, with its intent, knowledge, and encouragement, and Mylan will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '318 patent.

ANSWER: Denied.

33. Mylan's offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '318 patent, of the galantamine hydrobromide products for which approval is sought in ANDA No. 77-590, would actively induce and contribute to infringement of the '318 patent, and Mylan would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c). Mylan's use in the United States of the galantamine hydrobromide products in accordance with the labeling for which approval is sought in ANDA No. 77-590 prior to expiration of the '318 patent would infringe the '318 patent, and Mylan would be liable as an infringer under 35 U.S.C. § 271(a).

ANSWER: Denied.

34. Mylan had actual and constructive notice of the '318 patent prior to filing its ANDA No. 77-590, and Mylan's infringement of the '318 patent has been, and continues to be, willful.

ANSWER: Mylan admits that Mylan Pharmaceuticals had knowledge of the '318 patent prior to the filing of Mylan Pharmaceuticals' ANDA for galantamine hydrobromide tablets. Mylan denies the remaining allegations of Paragraph 34.

35. Plaintiffs will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '318 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

* * *

Mylan denies all remaining allegations not specifically admitted herein. Mylan further denies that Plaintiffs are entitled to the relief requested or to any relief whatsoever.

SEPARATE DEFENSES

First Defense

The manufacture, use, sale, offer for sale, or importation of the galantamine hydrobromide tablets that are the subject of Mylan Pharmaceuticals' ANDA have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '318 patent.

Second Defense

The claims of the '318 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

Third Defense

The Court lacks personal jurisdiction over Mylan Laboratories.

Fourth Defense

Mylan Laboratories is not a proper party to this action.

Fifth Defense

The Complaint fails to state a claim upon which relief can be granted against Mylan Laboratories.

Sixth Defense

Plaintiffs' claim for willful infringement fails to state a claim upon which relief can be granted.

Seventh Defense

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

Defendants/Counterclaim-Plaintiffs, Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan"), for their Counterclaims against Plaintiffs/Counterclaim-Defendants Janssen Pharmaceutica N.V., Janssen, L.P. (collectively, "Janssen"), and Synaptech, Inc. (collectively, "Plaintiffs/Counterclaim-Defendants"), allege as follows:

The Parties

1. Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

2. Mylan Laboratories Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania and has its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

3. On information and belief, Janssen Pharmaceutica N.V. purports and claims to be a corporation organized and existing under the laws of Belgium, with its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

4. On information and belief, Janssen, L.P. purports and claims to be a limited partnership organized and existing under the laws of the State of New Jersey, with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

5. On information and belief, Synaptech, Inc. ("Synaptech") purports and claims to be a company organized and existing under the laws of the State of New York, with its principal place of business care of Schwartz & Salomon, P.C., 225 Broadway, New York, New York 10007.

Jurisdiction and Venue

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Mylan in this judicial district, and because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular and systematic contact with, this judicial district.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

Patent-in-Suit

10. On or about May 5, 1987, the United States Patent and Trademark Office issued U.S. Patent No. 4,663,318 ("the '318 patent"), entitled "Method of Treating Alzheimer's Disease," to Bonnie Davis.

11. Synaptech purports and claims to own, and have the right to enforce, the '318 patent.

12. Janssen purports and claims to be the exclusive licensee of, and have the right to enforce, the '318 patent.

13. On June 7, 2005, Plaintiffs/Counterclaim-Defendants sued Mylan in this judicial district alleging infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A).

First Claim for Relief
(Declaratory Judgment of Patent Non-Infringement)

14. Mylan asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

15. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the '318 patent.

16. The manufacture, use, sale, offer for sale, or importation of the galantamine hydrobromide tablets that are subject of Mylan Pharmaceuticals' ANDA have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '318 patent.

17. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the galantamine hydrobromide tablets that are subject of Mylan Pharmaceuticals' ANDA have not infringed, do not infringe, and would not, if manufactured,

used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '318 patent.

Second Claim for Relief
(Declaratory Judgment of Patent Invalidity)

18. Mylan asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

19. There is an actual, substantial, and continuing justiciable case or controversy between Mylan and Plaintiffs/Counterclaim-Defendants regarding the invalidity of the '318 patent.

20. The claims of the '318 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Patent Code.

21. Mylan is entitled to a judicial declaration that the claims of the '318 patent are invalid.

Prayer for Relief

WHEREFORE, Mylan respectfully prays for judgment in its favor and against Plaintiffs/Counterclaim-Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the galantamine hydrobromide tablets that are subject of Mylan Pharmaceuticals' ANDA have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '318 patent;

(b) Declaring that the claims of the '318 patent are invalid;

(c) Ordering that Plaintiffs'/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Mylan;

(d) Declaring this case exceptional and awarding Mylan its reasonable attorneys' fees and costs of these Counterclaims under 35 U.S.C. § 285; and

(e) Awarding Mylan such other and further relief as the Court may deem just and proper.

JURY DEMAND

Mylan demands trial by jury on all issues so triable.

Dated: July 21, 2005

MYLAN PHARMACEUTICALS INC. and
MYLAN LABORATORIES INC.

By: */s/ Mary B. Matterer*

Mary B. Matterer # 2696
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Ave., 10th Floor
Wilmington, DE 19801
Telephone: (302) 888-6800
Facsimile: (302) 571-1750
mmatterer@morrisjames.com

Of Counsel (admitted pro hac vice):
William A. Rakoczy
Christine J. Siwik
Amy D. Brody
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60610
Tel: (312) 527-2157
Fax: (312) 222-6321
wrakoczy@rmmslegal.com

Attorneys for Defendants/Counterclaim-Plaintiffs
Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of July, 2005, I electronically filed the foregoing document, **MYLAN PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Steven J. Balick, Esq.
John G. Day, Esq.
Ashby & Geddes
222 Delaware Avenue,17th Floor
Wilmington, DE 19801

Additionally, I hereby certify that on the 21st day of July, 2005, the foregoing document was served via email on the following non-registered participants:

George F. Pappas, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
gpappas@cov.com

/s/ Mary B. Matterer
Mary B. Matterer # 2696
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
(302) 888-6800
mmatterer@morrisjames.com

Attorneys for Defendants/Counterclaim-Plaintiffs
Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc.